

ATTACHMENT 21

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

SURGICAL INSTRUMENT SERVICE)
COMPANY, INC.,)
Plaintiff/)
Counter-Defendant)
vs.) Case No.
INTUITIVE SURGICAL, INC.,) 3:21-cv-03496-VC
Defendant/)
Counter-Claimant.)
-----)

REMOTE VIDEOTAPED DEPOSITION OF

AMANDEEP MAHAL, M.D.

Tuesday, March 14, 2023

Reported by:

NADIA NOWAKI,

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Remote videotaped deposition of
AMANDEEP MAHAL, M.D., Volume I, taken on behalf of
Defendant/Counter-claimant, with all participants
appearing remotely via videoconference and the
witness testifying from Omaha, Nebraska, beginning
at 9:39 a.m. and ending at 2:14 p.m. on Tuesday,
March 14, 2023, before NADIA NEWHART, Certified
Shorthand Reporter No. 8714.

use of the Da Vinci robot system for more and more of the general surgeries that were performed in the state of Michigan.

Q Are the surgeries you do in your current practice, are they considered general surgery, or are they considered part of gynecological surgery or both or neither?

I mean, where -- what specialty do you think they fall into?

A So I'm a surgical subspecialist and would never claim to be a general surgeon. General surgeons have a very different subset of specialties.

My particular field of interest is reconstruction and urinary incontinence of the female pelvis. And so urogynecology falls somewhere between general gynecology and urology.

Q Could you look, please, at paragraph 37. You say that (as read):

"Da Vinci surgery has become a staple and essential for many surgeons."

What is -- what has become essential about
Da Vinci surgery? Essential means -- what are --
what is your definition of essential in this

1 Q Have you heard that from surgeons?

2 A I have.

3 Q Do you have any reason to doubt the sincerity
4 of a surgeon who's told you that he or she needs to
5 have -- to be able to deploy the Da Vinci system in 11:36:08
6 order to do their surgeries safely?

7 A I wouldn't have any reason to doubt a doctor
8 who tells me that they require Da Vinci to do a
9 surgery safely.

10 Q Could you go, please, to paragraph 38. 11:36:20

11 Is it true that in your own practice, the
12 Da Vinci tool is something that you deem essential
13 to do certain procedures safely?

14 A I believe the Da Vinci surgery, especially in
15 the example pointed out here in paragraph 38 for a 11:37:29
16 sacrocolpopexy, in my hand, there's a safer way to
17 perform that procedure.

18 Q And that's because of the more precise
19 movement and better optics afforded by the Da Vinci
20 system; isn't that right? 11:37:47

21 A That, in addition to the delicate nature of
22 the area which I'm resecting.

23 Q I'd like to ask you -- I'm going to change
24 subjects a little bit -- not totally, but I want to
25 stay on the informed consent for a few more 11:38:25

1 numbers are?

2 A I would be remiss to even guess what the
3 numbers are.

4 Q Could you look, please, at paragraph 41. And
5 I'm going to ask you about the sentence which also 11:45:12
6 includes the first line on page 13. So paragraph 41
7 spans pages 12 and 13.

8 There's a sentence that begins at the bottom
9 of page 12, and it completes on the top of page 13.

10 There's a phrase (as read): 11:45:32

11 "...through hospitals' promotion of
12 their Da Vinci surgery programs and
13 through general media or word of
14 mouth."

15 Do you see that? 11:45:44

16 A I do see that.

17 Q What do you have reference to when you write
18 about hospitals' promotion of their Da Vinci surgery
19 programs?

20 A Right around 2019, I believe, two of the 11:45:57
21 outlying hospitals in Omaha, Nebraska purchased
22 Da Vinci X and Xi robots. And before that, there
23 were no options for robotic surgery kind of east of
24 the Missouri River.

25 After those were purchased, you could see 11:46:19

1 billboards going down the interstate advertising
2 the -- you know, the new robotics program that was
3 available in these two hospitals.

4 And as such, as patients came into my office
5 in the subsequent months and years, there was more 11:46:36
6 and more discussion as to this robotic program, it
7 wasn't something that I was doing, et cetera.

8 Q Is it consistent with your experience to talk
9 about increasing awareness of robotic surgery as one
10 of the features of the medical environment these 11:47:04
11 days?

12 MR. VAN HOVEN: Objection to form.

13 THE WITNESS: When you mean to speak of, do
14 you mean out in the community with friends? Do you
15 mean with patients? If you could specify, I could 11:47:18
16 help answer that.

17 BY MR. RUBY:

18 Q Sure. Just reading paragraph 41 where you
19 say "robotic surgery becomes more publicly known,"
20 et cetera, are you writing about a phenomenon that 11:47:34
21 you would describe as heightened awareness of
22 robotic surgery and the impact that it might have in
23 respect to the certain kinds of medical treatment?

24 A I believe that over the last -- or over the
25 span of my career even, more and more, I receive 11:47:58

1 Q And you also in this paragraph use the word
2 "service." You used it a couple of times.

3 And what I'd like to do -- and then we'll
4 take a break -- we can take it now if you want. But
5 I'd like to get your -- the definition you use for 12:06:34
6 these terms that appear not infrequently in your
7 report.

8 So when you say that -- the phrase
9 "laparoscopic instruments that have been
10 serviced" -- that's in that paragraph -- what does 12:06:53
11 it mean to you, as the author, that has been done to
12 that laparoscopic instrument? It's had a paint job?
13 It's been sanded? It's been replanted?

14 I'm not trying to make light of this, but it
15 will save time if we have a common vocabulary so -- 12:07:08

16 A All right.

17 Q -- what's --

18 A Sorry, I cut you off. I said I wouldn't. Go
19 ahead.

20 Q No. So what does it mean to you, as the 12:07:17
21 author of this, to say that an instrument has been
22 repaired? What has -- what has been done to that
23 instrument in your use of that term?

24 A So this report I put together based on, like
25 I said, the materials that I've reviewed, as well as 12:07:39

1 my own clinical experience.

2 And when I say that I know that hospitals
3 sometimes send out their instruments for, you know,
4 whatever, retooling, repair, refurbish, what I mean
5 by that is, I have said or the hospital has decided 12:07:54
6 that an instrument is not functioning up to what it
7 needs to and it needs to go out for repair work.

8 But throughout the report, I do tend to use
9 the term "serviced," "repaired," "refurbished"
10 somewhat interchangeably, because to me, as a 12:08:13
11 practicing surgeon, it doesn't -- it doesn't -- it
12 doesn't affect the end use of the product for me.
13 And those terms kind of don't have a lot of the
14 bearing to my actual practice.

15 Q Before you begin a surgery using the Da Vinci 12:08:27
16 tools, do you personally conduct any kind of
17 pre-operative check or inspection of the
18 instruments?

19 A Before I start a surgery, I ask to look at
20 the panel of tools that have been given to me. But 12:09:00
21 before starting the surgery, I don't do any specific
22 control check on the instruments themselves other
23 than to make sure they are available in the
24 operating room.

25 Q What is a panel of tools? I'm sorry I 12:09:13

1 A Yes.

2 Q Is -- strike that.

3 In your first report, is the term
4 "malfunctioning EndoWrist" synonymous with failure,
5 as you use those terms? 12:50:40

6 A Certainly, in the context of paragraph 61,
7 I'm using those two terms interchangeably so that --
8 those end uses where a malfunction or a failure
9 happens.

10 Q Would you look, please, at paragraph 62, and 12:50:59
11 in particular, the last sentence.

12 A Okay. Starting with, "Given the nearly
13 identical operation"?

14 Q Yes.

15 A I do see it. 12:52:39

16 Q All right. Were you asked in this engagement
17 to make any assumptions about what process would be
18 undertaken with instruments by a third-party vendor
19 if there were no usage counters?

20 A I'm not sure if I was asked specifically 12:53:16
21 about if there were no usage counters, but I did ask
22 to see any documentation or get an understanding of
23 what would be involved in this kind of repair
24 process, at least from a high level.

25 Q And what did you take away from that? 12:53:34

1 what -- what assumption did you make about what
2 would be done in what you call this high-level
3 repair process?

4 MR. VAN HOVEN: Objection to form.

5 THE WITNESS: Yeah, I would say with my -- 12:53:48
6 with my high-level review of the -- of the
7 evaluation and the repair process that would be
8 performed, it appeared that there was a very well
9 thought out and standardized approach to evaluating
10 even some of the more small components or pieces of 12:54:06
11 the EndoWrist devices and that they seemed to be a
12 reasonable way of going about the repair, though I
13 myself am not a, you know, engineering expert to
14 review those papers with any kind of technical
15 aspects. 12:54:23

16 BY MR. RUBY:

17 Q Well, did your study or evaluation of the
18 materials that were furnished to you that purported
19 to tell you about the content of the repair, so
20 called, what specifically did you think would be 12:54:54
21 done on the issue of -- excuse me -- sharpening of
22 the instruments?

23 A My -- again, without perfect recollection of
24 all those documents, it sounded like --

25 Q Sorry. 12:55:08

1 MR. VAN HOVEN: Objection to form.

2 THE WITNESS: Again, I wouldn't -- I don't
3 recall the specifics about what to do with broken
4 pieces or parts.

5 BY MR. RUBY:

12:57:24

6 Q You did see some materials, did you not, that
7 spoke about tensioning of the cables, getting the
8 tension correct?

9 A I believe there was discussion of tensioning
10 of the cables within those documents.

12:57:53

11 Q All right. And did you take away from your
12 reading of it that in some fashion, the cables going
13 through the quote/unquote repair process, were
14 supposed to be evaluated for the correct tension in
15 the cables, and if it was incorrect, that they would
16 be properly tensioned? Is that, from a high level,
17 what they said?

12:58:17

18 A That's my understanding of how they were
19 going about the repair.

20 But again, here, my goal was not to
21 understand every piece or aspect of the repair
22 process that was being done but to see if there was,
23 for the most part, a comprehensive review from what
24 I worried about, as far as looking at those
25 instruments and seeing if they were appropriate to

12:58:33

12:58:55

1 be put back in use.

2 Q Could go, please, to paragraph 72.

3 A Sure.

4 Q I mean, is this -- strike that.

5 Does paragraph 72 summarize some of the 01:00:13
6 concepts you've been explaining to me for the last
7 few minutes? You were looking for quality
8 standards, and you were looking to get information
9 about how those standards were going to be met if a
10 third-party vendor was part of the process? 01:00:41

11 MR. VAN HOVEN: Objection to form.

12 THE WITNESS: I think paragraph 72 helps to
13 summarize the goal and in some ways the lens of
14 which I use to prepare this report, which was to
15 think of myself as someone who was asked to use 01:01:02
16 these instruments, what would I want to know about
17 and would these be things that I would be
18 comfortable using?

19 And like all instruments that I use, I rely
20 on the hospital system to go through their usual 01:01:17
21 forms and go through their usual kind of safety
22 checks to provide me with instruments that are
23 appropriate for use in the OR.

24 Q If you'd look, please, at the -- did I give
25 you a chance to read through paragraph 72 to 01:01:56

1 Exhibit 285 or should I take it off the Veritext?

2 Q 285 is the complaint? You can put it aside
3 for now.

4 A Thank you.

5 Q Yeah. Oh, and -- yes.

01:37:35

6 A Yeah, I've got 33 in front of me.

7 Q Okay. Is RAS an abbreviation for
8 robotic-assisted surgery?

9 A Yes.

10 Q In the substance of paragraph 33, you opine
11 that (as read):

12 "...some surgeons have gone to
13 offering only RAS and would convert
14 to open surgery if there was an
15 issue during the procedure. In such
16 instances, laparoscopic surgery
17 would not be an option."

18 What is your basis for this opinion?

19 A My basis is my experience with the surgeons
20 in the surrounding community of Omaha and that some
21 of them have taken to relying on the robot for most,
22 if not all, of their surgeries and would be unable
23 to convert to a laparoscopic surgery in those
24 instances.

01:38:30

01:38:48

25 Q Would you look, please, at paragraph 36.

01:39:02

1 into the -- you know, the minutia of trans identity
2 and how we address those kind of situations.

3 And then the final four years of my training
4 was, again, exclusively on females for
5 reconstructive surgery. 01:46:17

6 Q In terms of superiority of the Da Vinci
7 technique and tools, as you've testified to it
8 already today, do you perceive any differences in
9 the gender of patients? Is the robot more
10 important, in your opinion, to the surgical 01:46:39
11 treatment of men than women or women than men?

12 A I think it would be equally important for
13 both men and women given some gender-specific
14 surgeries that are now performed more frequently
15 with the robot, prostatectomy being one I gave an 01:47:01
16 example of in my report.

17 Q What is the basis for your opinion that the
18 Si and Xi systems provide similar advantages for
19 most surgery?

20 A The basis of the opinion -- and, again, it's 01:47:38
21 not all-encompassing -- comes from my own clinical
22 experience with both the S, the Si, as well as the X
23 and Xi platforms while out in independent practice.

24 And as the hospitals around my community
25 changed over from Si to X and Xi platforms, I do not 01:47:52

1 clinically see a difference in my operative times,
2 the rare but possible complications or the setup
3 times for myself with surgery, as well as the other
4 surgeons in the community that I spoke with.

5 Q Would you look, please, again, at 01:48:13
6 paragraph 62 in your first report.

7 A Yeah, I'm seeing it.

8 Q Okay. Now, you say in paragraph 62 (as
9 read):

10 "...there is no reason to believe 01:49:04
11 that an EndoWrist instrument that
12 has been serviced after expiration
13 of the Intuitive specified use
14 counter would not operate in the
15 same manner as an EndoWrist whose 01:49:16
16 use counter has not expired."

17 What's the basis for that opinion, please?

18 A So I've based this opinion based on a review
19 of the documents that were provided for me; and in
20 addition, my own surgical practice and understanding 01:49:35
21 of failures that have been reported at the hospital.

22 Q Have you ever done surgery with an EndoWrist
23 instrument beyond its tenth surgery?

24 A I have not done surgery past that expiration
25 date, but I have experienced failures and problems 01:50:08

1 with EndoWrist within their expiration counters.

2 Q Did you ever -- strike that.

3 Have you ever read or read the contents of
4 testing, if any, done by Intuitive beyond ten uses
5 of EndoWrist instruments? 01:50:44

6 A I am aware that there has been testing done,
7 though I'm not sure -- well, I am sure that I've
8 never seen that data through my work with this case
9 or elsewhere as far as like training or exercising
10 devices to a fatigue or a failure point. 01:51:03

11 Q Have you asked anybody to let you see those
12 tests, test results?

13 A In the basis of forming my opinion, I asked
14 to see what kind of testing was performed by
15 Intuitive. And I was given information that I've 01:51:23
16 cited in my work and my expert opinion. Most of
17 those tests were done up to the typical use of --
18 you know, I believe it's ten uses for most of them.

19 I do recall a specific example where there
20 was a deposition of a person who mentioned testing 01:51:40
21 that went beyond that during the engineering phase
22 of the EndoWrist instruments.

23 Q Do you consider yourself an expert in the
24 formatting and evaluation of failure testing of
25 medical devices? 01:52:06

1 A I am not an expert in the testing and failure
2 testing, nor am I an expert in the statistics that
3 go along with that. I simply used those paragraphs
4 and that information to inform what I already know
5 about the fail rate and the use of these products 01:52:23
6 for the end user, namely, the surgeon and the
7 patient.

8 Q What is off-label usage of a medical device,
9 generally?

10 A Right. To just couch that, even though 01:53:07
11 you've already said "generally," I am not an expert
12 in the FDA. But what I would say is when the FDA
13 clears certain devices or medicines, they often do
14 so with labeling or information regarding the use or
15 why this was approved. 01:53:25

16 If at any point a medicine is used outside of
17 those confines or a device is used outside of those
18 confines, that would be considered off-label use,
19 which happens throughout medical practice.

20 Q What importance, if any, do you assign to 01:53:48
21 the -- the presence or absence of FDA clearance for
22 a particular use of a medical device?

23 MR. VAN HOVEN: Objection to form.

24 THE WITNESS: I think that FDA clearance for
25 a medical device is something that we use and know 01:54:12